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The Prognosis of Optical Coherence Tomography-Guided Versus Intravascular Ultrasound-Guided Implantation of Drug-Eluting Stents: A Meta-Analysis from Randomized Controlled Trials

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Research Article

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ABSTRACT

Objective: Some observational studies and a few meta-analyses have shown a similarity of Optical Coherence Tomography (OCT) in guiding Drug-Eluting Stent (DES) implantation compared with Intravascular Ultrasound (IVUS). However, a comparison of long-term outcomes between guidance OCT or IVUS from Randomized Controlled Trials (RCTs) is lacking. This study aimed to compare the prognosis of IVUS *vs*. OCT in guiding stent implantation.

Methods: Randomized Controlled Trials (RCTs) related to compare long outcomes of IVUS versus OCT in guiding stent implantation from inception to 15 October 2023 were identified using PubMed, Cochrane Library, Medline, Web of Science and EMBASE databases. Two researchers independently screened articles, extracted data, and assessed the quality of each study according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Data were aggregated for the primary outcome measure using the random-effects model as pooled Risk Ratio (RR). The primary clinical prognosis including Major Adverse Cardiac Events (MACEs), all-cause mortality, all-cause myocardial infarction, all revascularization, and stent thrombosis.

Results: Five RCTs (3,339 patients) were included (OCT guidance=1,680; IVUS guidance=1,659). There were similar results for all long-term outcomes between OCT and IVUS-guided DES implantation: Major adverse

cardiac events (Relative Risk (RR)=0.96; 95% Confidence Interval (CI), 0.68-1.36; P=0.82), all-cause mortality (RR=1.00; 95% CI, 0.52-1.91; P=1.00), all-cause myocardial infarction (RR=0.81; 95% CI, 0.44-1.49; P=0.50), all revascularization (RR=1.02; 95% CI, 0.74–1.42; P=0.88), and stent thrombosis (RR=0.44; 95% CI, 0.10–1.97; P=0.28).

Conclusion: This meta-analysis suggested no significant difference in prognosis between OCT-guided *vs*. IVUS-guided coronary stent implantation.

Keywords: Drug-eluting stent; Intravascular ultrasound; Optical coherence tomography; Meta-analysis; Prognosis

INTRODUCTION

With the development of intravascular imaging and new insights into physiology, Optical Coherence Tomography (OCT) and Intravascular Ultrasound (IVUS) are being used increasingly in Percutaneous Coronary Intervention (PCI). Compared with coronary angiography, they can guide morphologic evaluation of target lesions, stent sizing, and expansion. OCT and IVUS have advantages and disadvantages. IVUS uses ultra-sound (-40 mm wavelength at 40 MHz), whereas OCT uses infrared light (1.3 mm wavelength), So OCT is superior to IVUS in terms of resolution and imaging depth (OCT:10-20 μm, IVUS:100-200 μm). Therefore, OCT can detect the microstructures of atherosclerotic plaques, such as fibrous caps, lipid cores, and thrombi, which represent important features of plaque vulnerability. However, OCT has less penetration of tissue (OCT : 1-2 mm; IVUS : 5-6 mm) and usually does not show the true blood vessel size at the lesion site. Some retrospective studies and meta-analyses have shown that OCT- and IVUS-guided PCI have cardiovascular-equivalent clinical outcomes, but are underpowered because Randomized Controlled Trials (RCTs) have not been done recently [1-4].OCT and IVUS are being used more widely in PCI and guidelines and increasingly consensus statements are recommending them for optimal PCI [5]. However, the evidence base for comparing these 2 imaging approaches during implantation of a Drug-Eluting Stent (DES) for coronary disease is lacking [6]. Meta-analyses from RCTs to compare the long-term clinical outcomes of OCT- *vs*. IVUS-guided PCI are lacking, hence the premise of our study.

MATERIALS AND METHODS

Literature search

PubMed, Cochrane Library, Medline, Web of Science and EMBASE databases from inception to 15 March 2022 were searched. A combination of several relevant terms was employed to ensure that all studies were included in the literature search: “ultrasonography, intravascular” “intravascular ultrasound” “intravascular ultrasound-guided” “IVUS” “IVUS-guided” “OCT” “optical coherence tomography” “optical coherence tomography-guided” “OCT-guided,” “drug-eluting stent” “sirolimus-eluting stent” “paclitaxel-eluting stent” “everolimus-eluting stent” “zotarolimus-eluting stent” “stent” and “DES”. The title and abstract, as well as the full text of the original article, were screened independently and verified by 2 researchers (Shuaifeng Sun and Shen Wang) (Figure 1).

Inclusion and exclusion criteria

The inclusion criteria were: (1) Patients with non-ST segment acute coronary syndrome and stable angina must be ≥ 18 years to undergo PCI using a DES; (2) RCTs must include comparisons of OCT-guided and IVUS-guided DES implantation with clinical follow-up ≥ 8 months; (3) Coronary-artery lesions must include long *de novo*, bifurcated,

chronic total occlusion, unprotected left-main, or a composite of all these lesions. Studies with insufficient data, systematic reviews, retrospective studies, case reports, and meta-analyses were excluded.

Data extraction and quality assessment

Two authors (Shuaifeng Sun and Shen Wang) reviewed all relevant articles to assess their eligibility. The following data were extracted from each included study: First author's name, title of the trial, publication year, baseline demographics, procedural characteristics, and clinical outcomes during follow-up. A third reviewer (Yue Wang) resolved disagreements between Shuaifeng Sun and Shen Wang. The quality of all RCTs was assessed using the Risk of Bias tool from the Cochrane Collaboration (www.cochrane.org/).

The definition and study endpoints

Non-ST segment acute coronary syndrome including acute Non-ST Elevation Myocardial Infarction (NSTEMI) and Unstable Angina Pectoris (UAP). Acute myocardial infarction is defined as acute myocardial injury with clinical evidence of acute myocardial ischemia and elevated and cardiac troponin levels that exceed the 99th percentile of the upper limit of normal reference values at least and combined one of the following: Symptoms of myocardial ischemia, new ischemic electrocardiogram changes, pathological Q-waves, imaging evidence suggesting loss of new viable myocardium or new local wall motion abnormalities consistent with ischemic etiology, or coronary thrombosis detected by angiography or autopsy. Unstable angina includes incipient angina, aggravating exertional angina and resting angina with ischemic changes on the ECG [7]. The primary endpoint of our study was the prevalence of Major Adverse Cardiac Events (MACEs), including all-cause mortality, all-cause Myocardial Infarction (MI), and all revascularization (including Target-Lesion Revascularization (TLR) and Target-Vessel Revascularization (TVR)). A MACE was defined as a composite of all-cause mortality, all-cause MI, TLR, or TVR according to the definition set by the Academic Research Consortium [8].

Statistical analysis

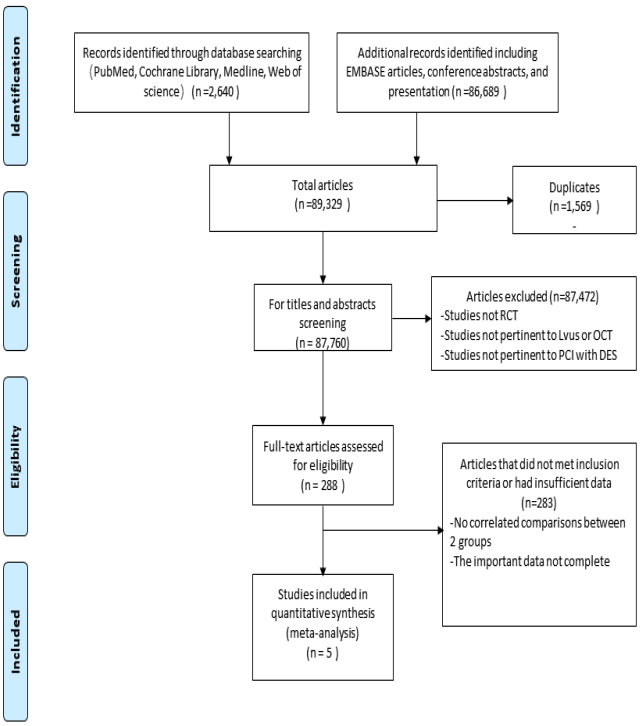
For baseline data, continuous variables were measured using the independent-sample t test using mean ± SD (standard deviation). Classification variables were measured using the ratio of chi-square statistics. All endpoints were assessed by Relative Risk (RR) with 95% Confidence Intervals (CIs). Chi-quare tests and I2 statistics were employed to assess heterogeneity between RCTs. If the P value of the Q test was<0.10 and/or I2 was ≥ 50%, significant heterogeneity was considered and a random-effects model was selected. If not, a fixed-effects model was used instead. We searched for an underlying publication bias using Egger's linear regression analysis. P<0.05 (2-tailed) was considered significant. Statistical analyses were undertaken using STATA 12.0 (STATA, College Station and State of Texas, USA).

RESULTS

Included studies

The search strategy is shown in Figure 1. Initial screening identified 89,329 results. After eliminating duplicates, 87,760 results were withheld for title and abstract screening and 288 results were selected for further full-text evaluation. Finally, five RCT studies with 3,339 participants were included (1,680 patients in the OCT-guided group and 1,659 patients in the IVUS-guided group) in this meta-analysis is shown in Figure 1 [9-14].

Figure 1. Flowchart of the literature search process. **Note:** DES: Drug-eluting stent; IVUS: Intravascular ultrasound; OCT: Optical coherence tomography; PCI: Percutaneous coronary intervention; RCT: Randomized controlled trial.



Patient and procedural characteristics

Table 1 shows the baseline characteristics of patients in the five RCTs included in this study. The clinical follow-up of patients in these five RCTs was a minimum of 8 months and a maximum of 3 years. There were no significant differences in baseline characteristics between the IVUS-guided group and OCT-guided group. Table 2 shows the characteristics of the surgical procedure (including the access site, lesion characteristics, and stent length) between the IVUS-guided group and OCT-guided group [9-12,14]. The most common site of vascular puncture in both groups was the radial artery. The left anterior descending artery had the largest proportion of target lesions: 52.3% in the OCT-guided group and 47.6% in the IVUS-guided group (Table 1).

Table 1. Study design and baseline characteristics of included RCTs.

First author	Kubo [12]	Muramatsu [10]	Ali [9]	Chamié [11]	Kang [14]
Year	2017	2020	2021	2021	2023
Sample size, n	412/405	54/55	158/146	51/50	1005/1003
Follow-up	8 months	3 years	1 year	2.5 years	1 year
Age	69/68	72/71	66/66	59.92/59.32	64.3/65.2
Male, n (%)	315 (76.5)/322 (79.5)	41 (75.9)/44 (80.0)	109 (69.0)/107 (73.0)	31 (60.8)/36 (72.0)	790 (78.6)/785(78.3)
Smoker, n	67/73	22-Dec	28/19	17/14	217/189
DM, n	169/165	27/24	52/55	17/20	325/345
Hypertension, n	315/299	34/39	124/113	46/42	647/639

Hyperlipidemia, n	316/321	43/36	115/107	36/30	840/841
LVEF (%)	NA	58/57	NA	NA	60.5/60.1
Prior PCI, n	140/140	24/26	11-Aug	NA	226/202
Prior CABG, n	07-Sep	0/0	03-Nov	NA	33/18
Prior MI, n	70/61	19/16	35/29	09-Oct	78/63

Table 2. Procedural characteristics in the included RCTs.

Variables	Kubo (OPINION)[12]	Muramatsu (MISTIC-1)[10]	Ali (ILUMIEN Ⅲ)[9]	Chamié (iSIGHT)[11]	Kang[14]
Arterial access, n					
Radial	NA	52/54	104/87	39/38	639/638
Brachial	NA	06-Apr	NA	NA	NA
Femoral	NA	04-Jun	54/59	NA	366/365
Coronary arteries, n					
Right coronary artery	102/117	18/22	35/36	20/19	NA
Left anterior descending	223/197	31/25	80/68	19/22	NA
Left circumflex	84/87	13/17	43/42	12-Oct	NA
Lesion characteristics					
Thrombus, n	04-May	0/2	02-Feb	01-Mar	NA
Bifurcation, n	154/157	NA	NA	08-Jun	516/540
Moderate-heavy calcification, n	29/51	Oct-16	32/24	Sep-13	76/76
Long lesion (>28 mm), n	56/54	NA	NA	NA	575/594
ACC/AHA lesion type B or C, n	329/319	26/30	NA	NA	NA
Multivessel disease, % or n	NA	20/24	NA	NA	608/629
Bifurcation lesions, % or n	37.4/38.8	NA	NA	15.7/11.7	516/540
Chronic total occlusion, % or *n*	NA	NA	NA	NA	56/52
Diameter of reference vessel, mm	2.62/2.59	2.69/2.75	2.78/2.87	2.82/2.85	NA
Pre-intervention MLD, mm	2.82/2.85	1.06/1.04	0.99/1.03	0.76/0.80	NA
Pre-intervention diameter stenosis, %	64/65	58.5/59.0	64.1/63.7	73.00/71.49	NA
Lesion length, mm	17.73/17.56	11.7/11.1	15.5/15.3	21.61/23.1	NA
Total stented length, mm	25.9/24.8	18.2/18.1	18.2/18.1	28.57/32.51	47.2/47.8
Post-dilation, n	316/304	316/304	NA	51/51	931/917

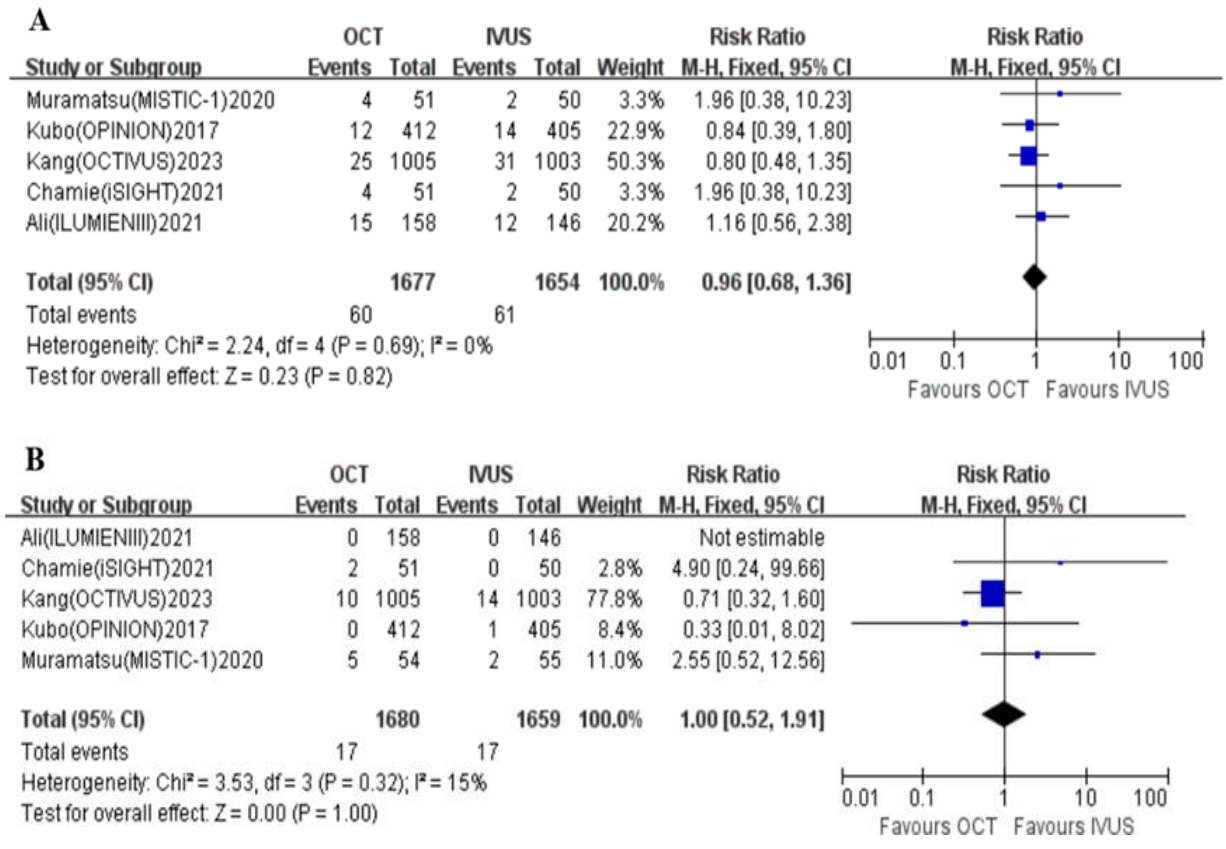
Note: All data are arranged in OCT/IVUS format.

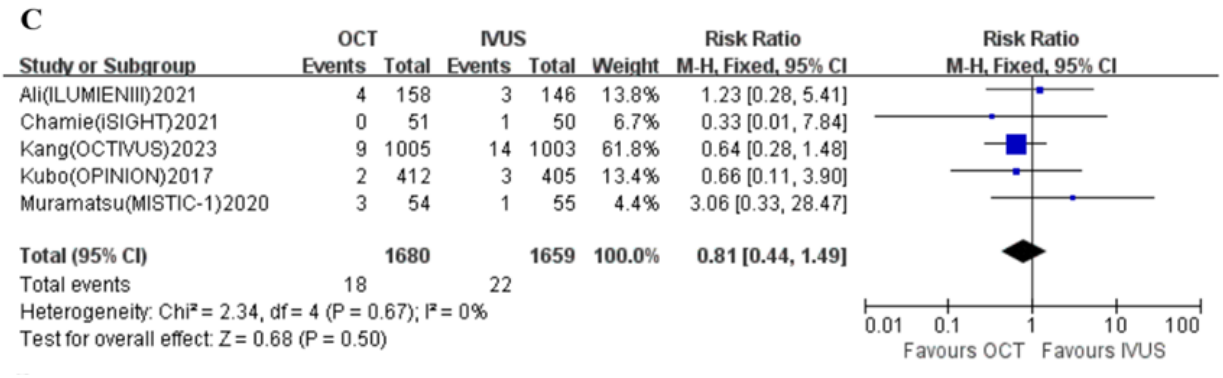
ACC: American College of Cardiology; AHA: American Heart Association; IVUS: Intravascular Ultrasound; MLD: Minimum Lumen Diameter; NA: Not Available; OCT: Optical Coherence Tomography; RCT: Randomized Control Trial.

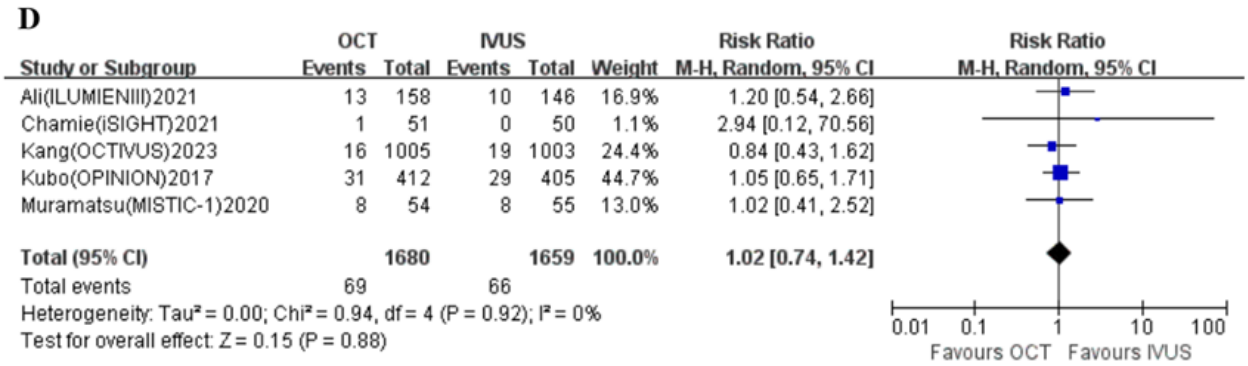
Clinical outcomes

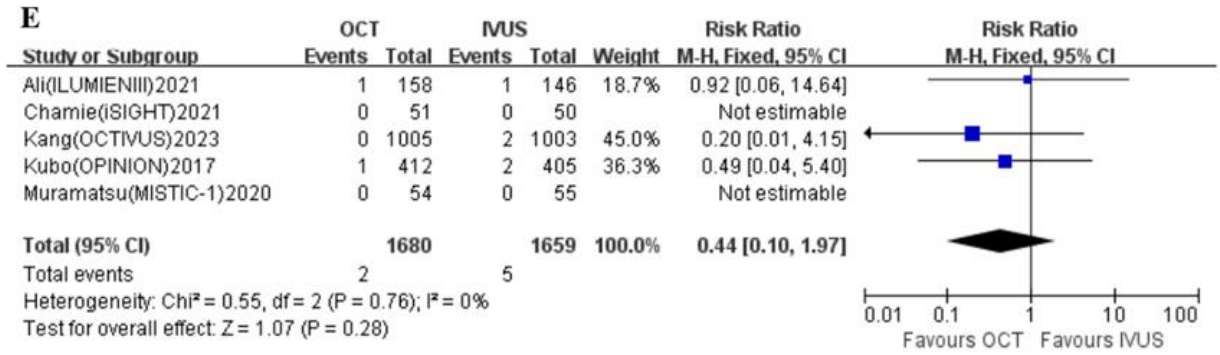
Figure 2 shows the clinical outcomes of the 2 groups [9-12,14]. The definition of MACE was slightly consistent across the five RCTs, including all-cause death, all-cause MI, TLR, and TVR [8]. MACEs were reported in all five RCTs. There were no significant differences between the 2 groups in terms of MACEs (HR=0.96; 95% CI: 0.68-1.36; P=0.82) with no significant heterogeneity among included studies (I2=0; P=0.69) (Figure 2A). With regard to all-cause mortality, the five RCTs demonstrated that OCT-guided DES was not superior to IVUS-guided DES, and there was no significant difference in all-cause mortality between the 2 groups (HR=1.00; 95% CI: 0.52-1.91; P=1.00). There was no significant heterogeneity among the five RCTs (I2=15%; P=0.32) (Figure 2B). The risk of all-cause MI was not significantly different between the 2 groups (HR=0.81; 95% CI: 0.44 to 1.49; P=0.50). There was no significant heterogeneity among the five RCTs (I2=0; P=0.67) (Figure 2C). The five RCTs were applied to analyses of all revascularization. There was no significant difference (HR=1.02; 95% CI: 0.74 to 1.42; P=0.88) and no significant heterogeneity (I2=0; P=0.92) between the 2 groups (Figure 2D). Data on stent thrombosis was reported in the five RCTs. With a mean follow-up of 1.79 years, the prevalence of stent thrombosis in the 2 groups was 0.12% (2 cases in the OCT-guided group) and 0.30% (5 cases in the IVUS-guided group). There was no reduction in the risk of stent thrombosis in the OCT-guided PCI group compared with that in the IVUS-guided PCI group (HR=0.44; 95% CI: 0.10 to 1.97; P=0.28), and there was no significant heterogeneity (I2=0; P=0.76) (Figure 2E) as shown in (Figures 2A-2E).

Figure 2. Forest plot of RR for MACEs (A), all-cause mortality (B), all-cause myocardial infarction (C), all revascularization (D), and stent thrombosis (E) associated with OCT-guided *vs*. IVUS-guided implantation of a drug-eluting stent. **Note:** Squares denote the effect size of individual RCTs; diamonds denote the summarized effect size; horizontal lines denote the upper and lower borders of the 95% CI. CI: Confidence interval; IVUS: Intravascular Ultrasound; MACEs: Major Adverse Cardiac Events; OCT: Optical Coherence Tomography; HR: Hazard Risk.









DISCUSSION

This meta-analysis of 3,339 patients from five RCTS showed no significant differences in prognosis (MACEs, all-cause mortality, all-cause MI, vessel revascularization, and stent thrombosis) between OCT-guided DES and IVUS-guided DES during a median follow-up of 1.79 years. Few meta-analyses have explored the impact of IVUS and OCT, but some observational studies have been completed [1,2]. This meta-analysis from RCTs to compare the long-term clinical outcomes of IVUS *vs*. OCT in directing PCI. The 1-year clinical outcomes reported recently in the ILUMIEN Ⅲ: OPTIMIZE PCI (Outcomes of Optical Coherence Tomography Compared with Intravascular Ultrasound and with Angiography to Guide Coronary Stent Implantation) trial has stated similar long-term clinical outcomes of OCT-guidance *vs*. IVUS-guidance in coronary-stent implantation [9].

The OPINION (Optical Frequency Domain Imaging *vs*. Intravascular Ultrasound in Percutaneous Coronary Intervention) trial demonstrated that the 12 month clinical outcome in patients undergoing OCT-guided coronary-stent implantation was non-inferior to patients who underwent IVUS-guided coronary stent implantation. The prevalence of target-vessel failure (a composite of cardiac death, all-cause MI, and TVR) was very low in the OCT-guided PCI group (5.2%) and IVUS-guided PCI group (4.9%) at 1 year follow-up [11]. The ILLUMEN Ⅲ: OPTIMIZE trial showed that the prevalence of MACEs and of any the single component (9.8% for OCT and 9.1% for IVUS) was not significantly different between OCT-guided PCI and IVUS-guided PCI. In addition, there was no significant difference in target-lesion failure (2.0% for OCT and 3.7% for IVUS). Conversely, there were no significant difference between OCT-guided PCI and IVUS-guided PCI in terms of minimum stent area, adhesion and intravascular image-related complications [9].

The MISTIC-1 (Comparison between Optical Frequency Domain Imaging and Intravascular Ultrasound for Percutaneous Coronary Intervention Guidance in Biolimus A9-Eluting Stent Implantation) non-inferiority trial was the RCT with the longest follow-up (3 years). Authors found that OCT-guided PCI was non inferior to IVUS-guided PCI in terms of in-segment minimum stent area ((4.56 ± 1.94) and (4.13 ± 1.86) mm^2 in the OCT group and IVUS group, respectively, P=0.43)) and neointimal healing score (median, 0.16 (interquartile range, 0-3.14) *vs*. 0.90 (0-3.30), respectively; P=0.43) at 8 months and clinical outcomes (hazard ratio, 1.05; 95% CI, 0.26 to 4.18; P=0.95) at 3 years [10]. The iSIGHT (Optical Coherence Tomography Versus Intravascular Ultrasound and Angiography to Guide Percutaneous Coronary Interventions) trial revealed that the prevalence of long-term MACEs (median follow-up of 2.5 years) was low and not significantly different between groups. Conversely, periprocedural complications and stent expansions under OCT guidance were noninferior to those using IVUS [11]. Observational studies have also explored the impact of IVUS and OCT for guidance during coronary-stent implantation. Kim et al [13] enrolled 290 patients who underwent implantation of a second-generation DES under OCT guidance (122 patients) or IVUS guidance (168 patients). OCT was superior to IVUS in terms of resolution and imaging depth. For example, tissue prolapse could be detected significantly more frequently (97.4% *vs*. 47.4%, P<0.001), along with more marginal dissection (10.5% *vs*.4.4%, P=0.078) and incomplete stenting (48.2% *vs*.36.8%, P=0.082). However, the researchers concluded that MACEs (3.5% *vs*.3.5%, P=1.000), stent thrombosis (0 *vs*. 0.9%, P=1.000), optimized stent placement (89.5% *vs*. 92.1%, P=0.492) and further intervention (13.2% *vs*.7.9%, P=0.234) showed no significant difference between the OCT-guided PCI group and IVUS-guided PCI group.

The OCTIVUS study from South Korea, led by Kang et al, is a prospective, multicenter, open-label, parallel RCT comparing the efficacy of OCT-guided *vs*. [14] IVUS-guided strategies for patients with stable angina or acute coronary syndrome. A total of 2008 patients are expected to be assigned randomly 1:1 to the OCT-guided PCI group or IVUS-guided PCI group. The primary endpoint event was target vessel failure defined as a composite end point of cardiac death, target vascular-associated myocardial infarction, or ischemic driven target vessel revascularization at 1 year after randomization. During the follow-up of 1-year, primary end point events occurred in 25 of 1005 patients in the OCT group and in 31 of 1003 patients in the IVUS group (P<0.001). Target-lesion failure in key secondary endpoints was also similar in the OCT-guided and IVUS-guided groups: At 1 year, 22 of 1005 patients in the OCT group (2.3%) and 29 of 1003 patients in the IVUS group (2.9%) had failed target lesions (P<0.001). The incidence of major complications of PCI was lower in the OCT group than in the IVUS group (22 (2.2%) *vs*. 37 (3.7%), P=0.047), and no complications related to imaging procedures were observed. The incidence of contrast induced acute kidney injury was similar (14 (1.4%) cases in OCT group *vs*. 15 (1.5%) cases in IVUS group, (P=0.85). The study concluded that in patients undergoing PCI for various coronary diseases, OCT-guided PCI was no worse than

IVUS-guided PCI in terms of composite endpoints of cardiac death, target vessel myocardial infarction, or ischaemic driven target vessel revascularization at 12 months after the first surgery. However, due to the lower than expected incidence of events, the statistical power of the study is not enough to draw definitive conclusions and so further research in this area is needed. The results of this RCT provide a valuable clinical evidence for the relative efficacy and safety of OCT-guided *vs*. IVUS-guided strategies in a broad population undergoing PCI in daily clinical practice [14].

Most experts agree that OCT provides not only clear histological images but also more accurate lumen measurements than IVUS. IVUS lumen area was larger than OCT (mean difference=0.41 mm^2, 12.5%). The Minimum Stent Area (MSA) evaluated under IVUS guidance (7.1 ± 2.1 mm^2) was significantly larger than under OCT guidance (6.1 ± 2.2 mm^2), in part because IVUS has better External Elastic Lamina (EEL) visualization compared to OCT, resulting in larger stent and balloon sizes [15,16]. OCT-guided PCI sequence required 17 to 70 ml more contrast agent to clear blood from the lumen than IVUS or angiography guidance. The inability to see the aorta-ostial (including ostial lesions) due to the need for blood clearance is an important limitation of OCT [17]. In terms of the occurrence of contrast nephropathy, the results of The OCTIVUS Randomized Clinical Trial found similar rates of OCT-guided PCI and IVUS-guided PCI, suggesting that we do not need to worry about the occurrence of CIN after PCI [14].

At present, the mainstream endovascular imaging technologies (IVUS and OCT) in clinical practice guide coronary interventional therapy, and are recommended as Class IIa in the European revascularization guidelines. Endovascular imaging OCT technology has always been regarded as an ideal tool to assist clinical research with its extremely high resolution, although it has been gradually recognized and used in clinical surgery in recent years. However, the clinical evidence-based medicine evidence of IVUS is significantly more than that of OCT. The value of OCT being widely used routinely in PCI still needs to be supported by more clinical research evidence.

CONCLUSION

The result from this meta-analysis of five RCTs (3,339 patients) suggested no significant difference in long-term outcomes between OCT-guided *vs*. IVUS-guided coronary implantation of a DES.

LIMITATIONS

This meta-analysis had two main limitations. Firstly, only five RCTs were included in our meta-analysis. Adequately powered, large-scale RCTs are needed. Secondly, the comparison between IVUS and OCT was limited to selected lesions, and may not be applicable to other, more complex lesions.

FUNDING

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AUTHOR CONTRIBUTIONS

Concept and design: Shen Wang and Xiaofan Wu; Supervision: Xiaofan Wu; Analysis and interpretation of data: Yue Wang and Fadong Li; Drafting of manuscript: Shen Wang; Literature search: Shen Wang and Shuaifeng Sun; Critical review: Xiaofan Wu.

DATA AVAILABILITY

The data underlying this article are available in the article.

CODE AVAILABILITY

Not applicable.

DECLARATIONS

Ethics approval

Not applicable.

Consent to participate

Not applicable.

Consent for publication

Not applicable.

Conflict of interest

The authors declare no competing interests.

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